Clinical Trials Office – Scope of Service

The Clinical Trials Office (CTO) facilitates clinical research by providing the USC researcher community with comprehensive administrative services that help move trials quickly from initial concept to study completion.

The CTO provides budget development, Medicare Coverage Analysis (MCA), contract negotiation and execution for industry-sponsored clinical trials, in addition to performing the MCA for non-industry sponsored clinical trials. The CTO, through Sponsored Projects Accounting (SPA), also invoices sponsors for clinical research costs and reimburses providers (e.g., Keck Medical Center, research pharmacy, clinical trials unit) for costs of services and goods used in the research.

Indirect Cost Rates and Contract Services by Sponsor and Agreement Type

Industry-Sponsored Clinical Trials (Sponsor or PI initiated)

The CTO provides budget development, coverage analysis and contract negotiation and execution for both Sponsor and Principal Investigator (PI) Initiated clinical trials funded by industry.

Industry-sponsored clinical trials are any research activity that involves a drug, device, or biologic, (test article) subject to prior submission to the FDA as part of an application for a research or marketing permit or is not subject to prior submission but is intended to be submitted later as part of an application for a research or marketing permit. Clinical trials are designed to determine efficacy and safety of the test article.

*Industry-sponsored clinical trials are assessed the Industry Clinical Trial indirect cost rate of 35% of Total Direct Cost (excluding certain fees).*

Industry Sponsored Drug or Device Agreements

These are instances where a sponsor provides a drug or device for a clinical trial, without funding from the sponsor. The agreement providing the drug or device will often have the same terms and conditions as sponsor-initiated clinical trial agreements (CTA).

The source of funding must be identified by the PI, department and/or School and the CTO will work with them to ensure resources are sufficient to conduct the trial, and to ensure compliance with regulations related to use of federal funds or other restricted funds.
Non-Industry Sponsored Clinical Research Projects with Patient Care

Non-industry sponsored clinical research projects are negotiated and executed by the Department of Contracts and Grants, Health Sciences Campus.

Currently, every clinical project, regardless of sponsor, involving patient care must be submitted to CTO for a Medical Coverage Analysis (MCA; see below). Once the MCA is completed, items chargeable to a third party insurance or Medicare are identified and attached to the completed MCA. CTO also conducts a consistency review with the approved Informed Consent Form (ICF) from the IRB to make sure that terms included in ICF with respect to payments and subject injury are consistent with the grant or contract terms accepted by the University.

For all non-industry sponsors, clinical trials are assessed the Federal Research indirect cost rate, which is currently 64% of Modified Total Direct Costs (MTDC). MTDC exclude patient care costs, equipment >$5,000 and some other specific items.

Confidentiality Disclosure Agreements (CDA)/Non-Disclosure Agreements (NDA) for Industry-Sponsored Clinical Trials

Clinical trial sponsors may require that the PI and/or study staff sign a Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) before reviewing confidential documents, such as the Investigator Brochure, Protocol, and other non-public or proprietary information, to evaluate USC’s interest in conducting the clinical trial. CDAs and NDAs assure that the sponsor that the institution will protect the confidential information against unauthorized disclosure for a period of time. The PI may acknowledge her or his responsibilities under the CDA, but only the CTO can execute the CDA on behalf of the University.

Budget Development and Negotiation

The CTO provides budget development and negotiation services for clinical trials funded by industry. For non-industry funded trials, budgets are developed within the administrative unit (division, department) of the PI. CTO Budgeting can provide assistance in identifying rates and costs for clinical services. Negotiation services are provided by the Department of Contracts and Grants, Health Sciences Campus.

A successful clinical trial will include a budget that adequately meets the financial needs for all research activities required to conduct the clinical trial. The CTO will work with the PI or Research Coordinator to ensure that the amount agreed upon by the Sponsor will adequately cover all costs associated with conducting a clinical trial. All final budgets will be approved and signed by the PI and Department Chair/Center Director, or designee.
For internally sponsored clinical research and trials, CTO conducts a MCA to identify study costs that fall under routine patient care costs, which would be chargeable to third party insurance or Medicare. All other costs must be borne by the project. The PI must provide an unrestricted account with sufficient balance to cover those costs that are not categorized as routine patient care. All final budgets will be approved and signed by the PI and Department Chair/Center Director, or designee.

**Medicare Coverage Analysis**

The CTO provides the MCA for clinical trials funded by both industry and non-industry sponsors, as well as internally sponsored clinical studies and trials.

An MCA determines whether a clinical trial meets the requirements for reimbursement by Medicare or other insurers for routine care costs. The MCA also determines *a priori* which items or services will be charged to a third party and which items will be charged to the research study. MCAs are required for all clinical research studies in which some items or services will be billed to a third party as part of standard medical care, whether the third party is Medicare or another provider. The MCA must be completed for such studies prior to contracting and prior to enrollment of study participants. Diagnostic or therapeutic patient care costs of a clinical trial include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care)

- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-approved chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service - in particular, for the diagnosis or treatment of complications.

Clinical studies and trials in which all charges are billed to the research project do not require an MCA. In such cases, all charges will be billed to the research project and none can be billed to third party payers.

**Post Award Billing**

The CTO, through SPA, provides account receivable management for clinical trials funded by industry. The CTO will collect based on the services rendered.
Post-award key functions provided by CTO include:

- Review the budget and payment terms and perform new account setup in Kuali system
- Create patient tracking logs
- Prepare, review, and submit invoices to sponsor as required by sponsor terms and conditions
- Review and monitor cash receipt vs. amount owed from sponsor
- Reconcile payments received from sponsor to study budget
- Internal billing and payment for items and services used in the study as follows:
  - Costs authorized and approved as part of trial or study processed against awards created in USC’s Kuali Financial System
  - Medical billings screened against approved budget, Research Order Form, current Informed Consent Form, and participant on and off study date
  - Monthly billings (i.e. pharmacy and CTU) screened against participant on and off study date
  - Charges allocated to third party or to study based on approved MCA
  - Work with the PI or Department Administrator to monitor that no incorrect or duplicate payments are made to the Hospital
  - Charges billed to study in accordance with the ROF, MCA and study budget and credited to the provider of the item or service using internal funds transfer
  - Dispute charges in cooperation with the PI and Department
- Perform administrative aspects of transferring and closing out funds at project completion